PUBLIC PROTECTION CABINET

Department of Insurance Division of Health and Life Insurance and Managed Care (New Administrative Regulation)

806 KAR 17:590. Annual report on providers prescribing medication for addiction treatment.

RELATES TO: KRS 304.1-050(1) 304.9-020, 304.9-055, 304.17A-005(29), 304.17A-700, 304.17A-732

STATUTORY AUTHORITY: KRS 304.2-110, 304.17A-732

NECESSITY, FUNCTION, AND CONFORMITY: KRS 304.2-110 authorizes the Commissioner of Insurance to promulgate administrative regulations necessary for or as an aid to the effectuation of any provision of the Kentucky Insurance Code as defined in KRS 304.1-010. KRS 304.17A-732 requires insurers to annually report to the commissioner the number and type of providers that have prescribed medication for addiction treatment to its insureds in conjunction with behavioral therapy and not in conjunction with behavioral therapy. This administrative regulation sets forth the format and submission time frame for the data reporting requirements in KRS 304.17A-732.

Section 1. Definitions.

- (1) "Commissioner" is defined by KRS 304.1-050(1).
- (2) "Department" is defined in KRS 304.1-050(2).
- (3) "Insurer" is defined by KRS 304.17A-005(29).
- (4) "Medication for addiction treatment" means a prescription drug that:
- (a) 1. Is prescribed for use in the treatment of alcohol or opioid addiction; and
- 2. Contains methadone, buprenorphine, or naltrexone; or
- 3. Was approved before January 1, 2022 by the United States Food and Drug Administration for the mitigation of opioid withdrawal symptoms.
 - (5) "Pharmacy Benefit Manager" is defined by KRS 304.9-020(15).

Section 2. Data Reporting Requirements.

- (1) (a) An insurer authorized to write health insurance in this state shall submit the data required by the Pharmacy Claims Standardized Data Request to the commissioner by March 31st of each year. A pharmacy benefit manger paying pharmacy claims on behalf of an insurer may submit the data required by the Pharmacy Claims Standardized Data request to the commissioner on behalf of the insurer.
 - (b) The data required by the Pharmacy Claims Standardized Data Request shall:
 - 1. Be submitted in an electronic format prescribed by the Commissioner;
 - 2. Contain the prescribed data elements and information in the order prescribed; and
- 3. Contain data for claims received in the prior calendar year for prescriptions for medication for addiction treatment.
- (2) (a) The Department shall generate and provide a Medical Claims Standardized Data Request to each insurer based on the data submitted pursuant to subsection (1) of this section
- (b) An insurer shall submit the data required by the Medical Claims Standardized Data Request within sixty (60) days of the date it is provided to the insurer, as described in paragraph (a) of this Section.
 - (c) The data required by the Medical Claims Standardized Data Request shall:

- 1. Be submitted in an electronic format:
- 2. Contain the prescribed data elements and information in the order prescribed; and
- 3. Contain data for claims of identified insureds, as requested by the commissioner, that were received in the prior calendar year.

Section 3. Material Incorporated by Reference.

- (1) The following material is incorporated by reference:
- (a) "Pharmacy Claims Standardized Data Request", 10/2021
- (b) "Medical Claims Standardized Data Request", 10/2021
- (2) This material may be inspected, copied, or obtained, subject to applicable copyright law, at the Kentucky Department of Insurance, Mayo-Underwood Building, 500 Mero Street, Frankfort, Kentucky 40601, Monday through Friday, 8 a.m. to 4:30 pm.

SHARON P. CLARK, Commissioner

RAY A. PERRY, Secretary

APPROVED BY AGENCY: October 13, 2021

FILED WITH LRC: October 14, 2021 at 3:30 p.m.

PUBLIC HEARING AND PUBLIC COMMENT PERIOD: A public hearing on this administrative regulation shall be held at 9:00 AM on December 21, 2021 at 500 Mero Street, Frankfort, Kentucky 40602. Individuals interested in being heard at this hearing shall notify this agency in writing by five workdays prior to the hearing, of their intent to attend. If no notification of intent to attend the hearing is received by that date, the hearing may be canceled. This hearing is open to the public. Any person who wishes to be heard will be given an opportunity to comment on the proposed administrative regulation. A transcript of the public hearing will not be made unless a written request for a transcript is made. If you do not wish to be heard at the public hearing, you may submit written comments on the proposed administrative regulation. Written comments shall be accepted through 11:59 PM on December 30, 2021. Send written notification of intent to be heard at the public hearing or written comments on the proposed administrative regulation to the contact person below.

CONTACT PERSON: Abigail Gall, Executive Administrative Secretary, 500 Mero Street, Frankfort, Kentucky 40601, phone +1 (502) 564-6026, fax +1 (502) 564-1453, email abigail.gall@ky.gov.

REGULATORY IMPACT ANALYSIS AND TIERING STATEMENT

Contact Person: Abigail Gall

- (1) Provide a brief summary of:
- (a) What this administrative regulation does: This new administrative regulation sets forth the format and submission timeframe for the data reporting requirements in KRS 304.17A-732.
- (b) The necessity of this administrative regulation: This administrative regulation is needed to adhere to the reporting requirements set forth in KRS 304.17A-732, which requires insurers to annually report to the commissioner the number and type of providers that have prescribed medication for addiction treatment to its insureds in conjunction with behavioral therapy and not in conjunction with behavioral therapy.
- (c) How this administrative regulation conforms to the content of the authorizing statutes: KRS 304.2-110 authorizes the Commissioner to promulgate administrative regulations relative to the Kentucky Insurance Code. In addition, KRS 304.17A-732 requires insurers to report this information to the Commissioner, and this regulation sets out the manner in which that reporting should be done, in an effort to provide clarity and promote efficiency.

- (d) How this administrative regulation currently assists or will assist in the effective administration of the statutes: This administrative regulation assists in the effectuation of KRS 304.17A-732, which was passed as Senate Bill 51 during the 2021 Regular Session.
- (2) If this is an amendment to an existing administrative regulation, provide a brief summary of:
- (a) How the amendment will change this existing administrative regulation: This is a new administrative regulation.
- (b) The necessity of the amendment to this administrative regulation: This is a new administrative regulation.
- (c) How the amendment conforms to the content of the authorizing statutes: This is a new administrative regulation.
- (d) How the amendment will assist in the effective administration of the statutes: This is a new administrative regulation.
- (3) List the type and number of individuals, businesses, organizations, or state and local governments affected by this administrative regulation: All insurers offering/transacting in health insurance in the state of Kentucky, as well as any Pharmacy Benefit Managers (PBMs) who manage pharmaceutical claims for health insurers offering pharmacy benefits.
- (4) Provide an analysis of how the entities identified in the previous question will be impacted by either the implementation of this administrative regulation, if new, or by the change, if it is an amendment, including:
- (a) List the actions each of the regulated entities have to take to comply with this regulation or amendment: Health Insurers/PBMs will need to provide the Commissioner with any pharmacy claims that include prescription codes for methadone, buprenorphine, or naltrexone by March 31st of each year. The insurer is then required, within 60 days of receipt of a request from the Commissioner, to provide medical claims data for the requested claims and member IDs identified by the Department.
- (b) In complying with this administrative regulation or amendment, how much will it cost each of the entities: There is no associated cost with this administrative regulation.
- (c) As a result of compliance, what benefits will accrue to the entities: Insurers and PBMs will be in compliance with statutory reporting requirements.
- (5) Provide an estimate of how much it will cost the administrative body to implement this administrative regulation:
- (a) Initially: Implementation of this amendment is not anticipated to have an initial cost on the Department of Insurance.
- (b) On a continuing basis: Implementation of this amendment is not anticipated to have an ongoing cost on the Department of Insurance.
- (6) What is the source of the funding to be used for the implementation and enforcement of this administrative regulation: The Department will use funds from its current operational budget to perform the tasks necessary.
- (7) Provide an assessment of whether an increase in fees or funding will be necessary to implement this administrative regulation, if new, or by the change if it is an amendment: There will be no increase in fees or funding to implement this new administrative regulation.
- (8) State whether or not this administrative regulation established any fees or directly or indirectly increased any fees: There a no fees that will be established.
- (9) TIERING: Is tiering applied? Tiering is not applied because this administrative regulation requires all insurers licensed to transact health insurance to report the same information to the department.

- (1) What units, parts or divisions of state or local government (including cities, counties, fire departments, or school districts) will be impacted by this administrative regulation? The Department as the implementer of this administrative regulation.
- (2) Identify each state or federal statute or federal regulation that requires or authorizes the action taken by the administrative regulation.
- (3) Estimate the effect of this administrative regulation on the expenditures and revenues of a state or local government agency (including cities, counties, fire departments, or school districts) for the first full year the administrative regulation is to be in effect. If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.
- (a) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for the first year? No revenue is expected to be generated.
- (b) How much revenue will this administrative regulation generate for the state or local government (including cities, counties, fire departments, or school districts) for subsequent years? No revenue is expected to be generated.
 - (c) How much will it cost to administer this program for the first year? No cost is expected.
- (d) How much will it cost to administer this program for subsequent years? No cost is expected.

Note: If specific dollar estimates cannot be determined, provide a brief narrative to explain the fiscal impact of the administrative regulation.

Revenues (+/-): Neutral Expenditures (+/-): Neutral

Other Explanation: